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DETAILED ACTION

Claim Status

1. Amendment filed on July 10, 2008 and the Declaration filed on July 29, 2008 is acknowledged. Claims 7, 10-14, 17 and 22 were examined in last action. Applicant has amended claims 7, 10-14, 17 and 22; added new claims 23-27. Of these new claims, claim 23 is drawn to assay method that is not elected invention, hence is withdrawn. Currently claims 7, 10-14, 17, 22 and 24-27 are active and will be examined in this action to the extent they read upon the elected primers of SEQ ID NOs 17 and 18 and their complement SEQ ID NO 7 and 8 respectively.

Response to Applicant's Arguments

Re Election/Restrictions

2. Applicant's request for rejoinder of group I methods is premature since at this time elected group II invention (product) has not yet been allowed. Upon allowance of the elected invention the question of rejoinder will be addressed.

Re Objections to claims 7, 10-14, 17 and 22

3. Amendment to claims 7, 10-14, 17 and 22 identify each oligonucleotide recited by its SEQ ID NO and hence obviating the objections raised in the last action.

Re 112 2nd rejection of claims 7, 10-14, 17 and 22

4. Amendment to claims 7, 10-14, 17 and 22 now specify that recited primers hybridize under high stringency condition, thus obviating the 112 2nd rejections cited previously. Accordingly 112 2nd rejection of claims 7, 10-14, 17 and 22 is withdrawn.

Re 103 rejection of claims 7, 10 and 13-14 over Matsumoto et al. in view of Buck et al.

5. Applicant's arguments filed July 10, 2008 have been fully considered but they are not persuasive. The cited art Matsumoto et al. teaches the sequence of the claimed SEQ IDS that are under examination. These are sequences from Pythium species. The sequence taught by Matsumoto et al. is a bigger region of Pythium sequences. Examiner has used Buck et al. to teach the concept that using a known sequence one of ordinary skill can design primers. Current position of Office is that absent any secondary considerations all these primers are equivalent.

In an attempt to overcome the obviousness rejection, Applicant has filed a declaration under C.F.R 1.132 to provide secondary considerations. The data and arguments of declaration applies to primers that are identified by their exact SEQ IDs in the declaration. These arguments presented in the declaration are persuasive with regard to exact sequences that Applicant has disclosed, namely the SEQ IDs claimed provide species specificity. However the data presented in the declaration also substantiates the fact that small changes in the sequences of the recited primers (single base additions to either the 5' or 3' end) results in loss of specificity.

In the instant recitation of claims, the claims under consideration are not limited to the recited SEQ ID Nos. but are claimed as primers which hybridize to an oligonucleotide of the recited SEQ ID Nos. In other words the claim language encompasses the primer that have single base additions to either the 5' or 3' end. Such primers that have single base additions to either the 5' or 3' end will hybridize to the claimed SEQ IDs but will not have the specificity required for the invention to work. Thus

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one of ordinary skill will end up making primers that will not function in the intended fashion. Hence the claims in present form are broader than the scope of claims to which the data provided in the declaration is applicable. In other words currently recited scope of the invention is not fully commensurate with the data provided in the declaration. For declaration to be persuasive to overcome the obviousness rejection, the scope of the claimed invention must be commensurate with the data presented. Therefore obviousness rejection of claims 7, 10 and 13-14 over Matsumoto et al. in view of Buck et al. are being maintained.

Re 103 rejection of claims 11-12, 17 and 22 over Matsumoto et al. & Buck et al. further in view of Inoko et al.

6. Since rejections of recited oligos over Matsumoto et al. & Buck et al. is being maintained. The rejection of claims 11-12, 17 and 22 further in view of secondary reference Inoko et al is also being maintained.

Claim interpretation

7. The claims under prosecution are product claims. The hybridization conditions recited for the claimed primers is functional language that describes how this product functions but do not add any further structural limitation to the claimed primer.

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Claim Objections

8. Claims 7, 10-14, 17, 22 and 24-27 are objected to as containing non elected subject matter. Only 4 SEQ IDS indicated above are elected for examination, the claim as currently recited contains non elected SEQ IDS. Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 11. Claims 7, 10, 13-14, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (2000). Mycol. Res. 104 (11):1333-1341 in view of Buck et al. (1999) Biotechniques 27: 528-536.

Regarding claims 7, 10, 13-14, and 24 Matsumoto, C., Kageyama, K. and Suga, H. teach

sequence of a region that comprises sequences that have 100% sequence homology to the claimed primers of SEQ ID NO 17 and its complement SEQ ID No 7 as well as SEQ ID No 18 and its complement SEQ ID No 8. See the alignment provided below.

```
RESULT 9
AB108008
LOCUS
           AB108008
                                    907 bp
                                              DNA
                                                      linear
                                                               PLN 15-APR-
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
           sequence, strain: Py77.
ACCESSION AB108008
           AB108008.1 GI:29837164
VERSION
KEYWORDS
SOURCE
           Pythium sylvaticum
 ORGANISM Pythium sylvaticum
           Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
           Pythium.
REFERENCE
           1
 AUTHORS Matsumoto, C., Kageyama, K. and Suga, H.
           Intraspecific DNA polymorphisms of Pythium irregulare
 TITLE
 JOURNAL Mycological Research 104, 1333-1341 (2000)
REFERENCE
           2 (bases 1 to 907)
           Kageyama, K. and Matsumoto, C.
 AUTHORS
 TITLE
           Direct Submission
 JOURNAL
           Submitted (11-APR-2003) Koji Kageyama, River Basin Research
Center,
           Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
           Fax:81-58-293-2062)
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     rRNA
                    291. .449
                    /product="5.8S ribosomal RNA"
                    450. .907
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 Best Local Similarity
                         100.0%; Pred. No. 0.52;
 Matches 21; Conservative
                               0; Mismatches
                                                 0;
                                                     Indels
                                                                   Gaps
0;
QУ
           1 CGCTGTGGTTGGTATATTTGT 21
                                         (SEQ ID NO 17= IXa)
              Db
         514 CGCTGTGGTTGGTATATTTGT 534
```

```
RESULT 9
AB108008/c
LOCUS
           AB108008
                                    907 bp
                                           DNA
                                                     linear PLN 15-APR-
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
           sequence, strain: Py77.
ACCESSION
           AB108008
           AB108008.1 GI:29837164
VERSION
KEYWORDS
SOURCE
           Pythium sylvaticum
 ORGANISM Pythium sylvaticum
           Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
           Pythium.
REFERENCE
 AUTHORS Matsumoto, C., Kageyama, K. and Suga, H.
          Intraspecific DNA polymorphisms of Pythium irregulare
 TITLE
 JOURNAL Mycological Research 104, 1333-1341 (2000)
REFERENCE 2 (bases 1 to 907)
 AUTHORS Kageyama, K. and Matsumoto, C.
           Direct Submission
 TITLE
 JOURNAL
           Submitted (11-APR-2003) Koji Kageyama, River Basin Research
Center,
           Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
           (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
           Fax:81-58-293-2062)
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                    /db xref="taxon:82950"
    misc RNA
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                    /note="internal transcribed spacer 1 (ITS1)"
     rRNA
                    291. .449
                    /product="5.8S ribosomal RNA"
                    450. .907
    misc RNA
                    /note="internal transcribed spacer 2 (ITS2)"
ORIGIN
                         100.0%; Score 21; DB 4; Length 907;
 Query Match
                         100.0%; Pred. No. 0.52;
 Best Local Similarity
 Matches 21; Conservative 0; Mismatches
                                                0; Indels 0; Gaps
0;
           1 ACAAATATACCAACCACAGCG 21
                                          (SEQ ID NO 7 = IVa)
QУ
             Db
         534 ACAAATATACCAACCACAGCG 514
```

```
RESULT 6
AB108008/c
                                    907 bp
LOCUS
           AB108008
                                              DNA
                                                      linear
                                                              PLN 15-APR-
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
           sequence, strain: Py77.
           AB108008
ACCESSION
           AB108008.1 GI:29837164
VERSION
KEYWORDS
           Pythium sylvaticum
SOURCE
 ORGANISM Pythium sylvaticum
           Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
           Pythium.
REFERENCE
           1
 AUTHORS
           Matsumoto, C., Kageyama, K. and Suga, H.
           Intraspecific DNA polymorphisms of Pythium irregulare
 TITLE
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 JOURNAL
REFERENCE
           2 (bases 1 to 907)
 AUTHORS Kageyama, K. and Matsumoto, C.
 TITLE
           Direct Submission
 JOURNAL
           Submitted (11-APR-2003) Koji Kageyama, River Basin Research
Center,
           Gifu University; 1-1 Yanaqido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
           Fax:81-58-293-2062)
FEATURES
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                    /strain="Py77"
                    /db xref="taxon:82950"
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                    /note="internal transcribed spacer 1 (ITS1)"
    rRNA
                    291. .449
                    /product="5.8S ribosomal RNA"
    misc RNA
                    450. .907
                    /note="internal transcribed spacer 2 (ITS2)"
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 Query Match
 Best Local Similarity 100.0%; Pred. No. 17;
 Matches 20; Conservative
                               0; Mismatches
                                                0; Indels
                                                               0; Gaps
0;
           1 GCCAATTGCACAAGTACAAA 20
                                         (SEQ ID NO 18 = IXb)
Qу
             Db
         843 GCCAATTGCACAAGTACAAA 824
```

```
RESULT 6
AB108008
LOCUS
           AB108008
                                    907 bp
                                              DNA
                                                     linear
                                                              PLN 15-APR-
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
           sequence, strain: Py77.
ACCESSION AB108008
           AB108008.1 GI:29837164
VERSION
KEYWORDS
           Pythium sylvaticum
SOURCE
 ORGANISM Pythium sylvaticum
           Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
           Pythium.
REFERENCE
           1
 AUTHORS
           Matsumoto, C., Kageyama, K. and Suga, H.
 TITLE
           Intraspecific DNA polymorphisms of Pythium irregulare
           Mycological Research 104, 1333-1341 (2000)
 JOURNAL
REFERENCE 2 (bases 1 to 907)
 AUTHORS Kageyama, K. and Matsumoto, C.
 TITLE
           Direct Submission
 JOURNAL
           Submitted (11-APR-2003) Koji Kageyama, River Basin Research
Center,
           Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
           Fax:81-58-293-2062)
FEATURES
                    Location/Qualifiers
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                    /mol_type="genomic DNA"
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                    /db xref="taxon:82950"
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     rRNA
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                    /product="5.8S ribosomal RNA"
                    450. .907
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                    /note="internal transcribed spacer 2 (ITS2)"
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 Best Local Similarity 100.0%; Pred. No. 17;
 Matches 20; Conservative
                              0; Mismatches
                                                0; Indels
                                                               0; Gaps
0;
           1 TTTGTACTTGTGCAATTGGC 20
                                         (SEQ ID No 8 = IVb)
Qу
             Db
         824 TTTGTACTTGTGCAATTGGC 843
```

Note the sequences of all the above primers 21 (SEQ ID No 17 and 7) and 20 (SEQ ID NO 18 and 8) bases long.

As indicated above Matsumoto et al. teach the region of Pythium species that encompasses the regions that are claimed as primers of the instant invention.

Regarding claim 7, Matsumoto et al. teach an 18- to 24-mer oligonucleotide primer (SEQ ID No 17 = IXa and SEQ ID No 18 = IXb) which hybridizes to an oligonucleotide sequence (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb) selected from the group consisting of formulae IVa, IVb, IXa, IXb.

Regarding claim 10, Matsumoto et al. teach the primer as claimed in claim 7, wherein said primer comprises a sequence selected from the group consisting of formulae IVa, IVb, IXa, IXb (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb; SEQ ID No 17 = IXa and SEQ ID No 18 = IXb).

Regarding claim 13, Matsumoto et al. teaches a primer composition comprising a pair of 18-24-mer oligonucleotide primers (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb) at least one of which <a href="https://www.hybridizes.com/hybridizes

Regarding claim 14, Matsumoto et al. teaches the primer composition as claimed in claim 13, wherein at least one of said pair is a primer comprising a sequence <u>selected</u> from the group consisting of formulae IVa, IVb, IXa, IXb (see above).

Regarding claim 24, Matsumoto et al. teaches the sequence of oligonucleotide as claimed in claim 7. The newly added claim further recites wherein said high stringency conditions comprise washing two times with SSC (0.15M NaC1, 0.015M

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sodium citrate, pH 7.2) at 65 °C. This added limitation refers to conditions under which the primer is used but it does not further add any structural limitation to the claimed primer, hence is not being considered further.

Regarding claim 26, Matsumoto et al. teaches the sequence of oligonucleotide as claimed in claim 13. The newly added claim further recites wherein said high stringency conditions comprise washing two times with SSC (0.15M NaC1, 0.015M sodium citrate, pH 7.2) at 65 °C. This added limitation refers to conditions under which the primer is used but it does not further add any structural limitation to the claimed primer, hence is not being considered further.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the sequences of Matsumoto et al. to design the **primer** claimed in instant application as SEQ ID No 17 and 18 for detection of SEQ ID No 7 and SEQ ID No 8.

In the recent court decision *KSR International Co. v. Teleflex Inc., 82* 127 SCt 1727 (2007), the U.S. Supreme Court determined that if the combination of the claimed elements was "obvious to try" by a person of ordinary skill, this might show that such a combination was obvious under §103. Regarding "obvious to try", the Court stated:

"A person of ordinary skill is also a person of ordinary creativity, not an automaton. The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

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The sequence of Pythium rDNA- interspecific region (ITS regions) are taught to one of ordinary skill by prior art. Matsumoto uses this sequence information to identify and classify the various Pythium species (see page 1339-phylogenetic analysis and one of ordinary skill in the art is capable of designing primer/probes useful for amplifying a given region of any nucleic acid whose sequence is known and detecting it using appropriate technique. PCR amplification is currently one of the fastest, cheapest way of detecting presence of any given nucleic acid, provided some information is available based on which amplification primers flanking the region to be amplified can be designed.

Since the claimed primers/probes simply represent structural homologs, which are derived from sequences suggested by the prior art as useful for primers of the Pythium interspecific region and concerning which a biochemist of ordinary skill would attempt to obtain suitable primers flanking the region of interest, the claimed primers are prima facie obvious over the cited references in the absence of secondary considerations.

Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533,

column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

12. Claims 11-12, 17, 22, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (2000). Mycol. Res. 104 (11):1333-1341 in view of Buck et al. (1999) Biotechniques 27: 528-536 further in view of Inoko et al. (WO 01/92572 A1 published June 12, 2001 with English equivalent document US 2003/0228585 A1 used for citing the exact lines and paragraphs).

Regarding claims 11, 12, and 25 Matsumoto et al. and Buck et al. teach 18- to 24-mer oligonucleotide primer and composition (SEQ ID No 17 = IXa and SEQ ID No 18 = IXb) which hybridizes to an oligonucleotide sequence (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb) selected from the group consisting of formulae IVa, IVb, IXa, IXb. (see above as described in detail for claim 7).

Regarding claim 12, 17, 22 and 27 Matsumoto et al. teach the primer (claim 12) or at least one primer (claim 17), at least one of said primer (claim 22) wherein said

primer comprises a sequence <u>selected from the group consisting</u> of formulae IVa, IVb, IXa, IXb (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb; SEQ ID No 17 = IXa and SEQ ID No 18 = IXb).

Regarding claims 11, 12, and 25, Matsumoto et al. and Buck et al. do not teach a substrate having immobilized thereon at least one oligonucleotide primer.

Regarding claims 11, 12, and 25, Inoko et al. teach a substrate having immobilized thereon at least one oligonucleotide primer. (see page 6, par. 0102 where primers immobilized on substrate are taught. By this teaching Inoko et al. teach a substrate having immobilized thereon at least one oligonucleotide primer).

Regarding claim 25, the claim further recites wherein said high stringency conditions comprise washing two times with SSC (0.15M NaC1, 0.015M sodium citrate, pH 7.2) at 65 °C. This added limitation refers to conditions under which the primer is used but it does not further add any structural limitation to the claimed primer, hence is not being considered further.

Regarding claims 17, 22 and 27 Matsumoto et al. teach a method of detecting fungal infection of soil or vegetables by pathogenic Pythium species (see Matsumoto et al. page 1333 par. 1 and Table where pathogenic Pythium species from vegetables and soil are described. See page 1334 where RFLP analysis of r DNA-ITS, RAPD analysis based on PCR amplification is taught as method of detecting Pythium species).

Regarding claims 17, 22 and 27, Matsumoto et al. and Buck et al. do not teach packaging of primers in a kit format for use of Pythium detection.

Regarding claims 17, 22 and 27, Inoko et al. teach primers for preparing a nucleic acid target can be included in an HLA typing kit together with a substrate on which oligonucleotides are immobilized. (see page 6, par. 0102).

Regarding claim 27, the claim further recites wherein said high stringency conditions comprise washing two times with SSC (0.15M NaC1, 0.015M sodium citrate, pH 7.2) at 65 °C. This added limitation refers to conditions under which the primer is used but it does not further add any structural limitation to the claimed primer, hence is not being considered further.

It would have been prima facie obvious to one of ordinary skill at the time the invention was made to package the primers of Matsumoto et al. and Buck et al. useful for detecting Pythium species in the kit format taught by Inoko et al. The motivation to do so is provided by Inoko et al. who state "A nucleic acid target for use in HLA typing is prepared by using the obtained DNA. The nucleic acid target can be prepared by amplifying a nucleic acid by using primers designed so as to correspond to a nucleotide sequence of capture oligo". (see page 6 par. 0097). They go on to state "Primers used for PCR are designed so that a nucleic acid target should include a complementary sequence of a capture oligo" (see page 6 par. par. 0098). Thus explicitly providing motivation to one of ordinary skill to design primers immobilized on substrate. The target amplified by these primers have a sequence that is complementary to capture oligos (Note SEQ ID NO 17 and 18 are complementary to SEQ ID No 7 and 8 in the instant application) that are specific for Pythium species to be detected. Given this teaching of Inoko et al. one of ordinary skill recognizes the advantage of having the appropriate

primers combinations and probes packaged in Kit format along with the instructions to use them.

Conclusion

- 13. All claims under consideration 7, 10-14, 17, 22 and 24-27 are rejected over prior art.
- 14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/ Primary Examiner, Art Unit 1637

Suchira Pande Examiner Art Unit 1637